



PATENT APPLICATION
OUR FILE NO. 960565.ORI

Part of
#14

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Re App: David M. Flynn et al.

Date: November 14, 2000

S.N.: 09/139,155

Art Unit: 2833

Filed: August 24, 1998

Examiner: Ross Gushi

For: ADAPTER INTEGRATED INTO A LEAD BODY

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REPLY BRIEF UNDER 37 C.F.R. § 1.193

In response to the Examiner's Answer ("the Answer") dated September 14, 2000, Appellants respectfully point out that the Answer has misstated the issues on appeal, erroneously contends that all claims stand or fall together, and fails to identify a *prima facie* case of obviousness. In particular with regard to obviousness, the Answer fails to demonstrate how the prior art reference (or references when combined) teach or suggest all the claim limitations. Further, the Answer fails to identify the suggestion or motivation to modify the references or to combine the reference teachings as asserted in the Answer.

ARGUMENT

I. A *PRIMA FACIE* CASE OF OBVIOUSNESS HAS NOT BEEN ESTABLISHED

A. The Cited References Do Not Teach Or Suggest All Limitations Of The Claimed Invention

Generally, the Answer has neglected to consider the claim as a whole, including all limitations. Thus, the Answer fails to consider the claims in their proper context. Particularly, the Answer does not recognize the novel and non-obvious aspects of Claims 1 and 9 requiring, *inter alia*, a lead having an adapter member extending from the lead wherein a terminal block within the connector port is connected by a jumper wire to the conductors of the main lead body.

These claimed limitations require novel and non-obvious aspects of Appellants' invention in view of the cited references.

Under sub-heading (10) Grounds for Rejection, the Answer contends that "what Appellant claims is a lead comprising an adapting member." (Examiner's Answer at Page 8, line 3). In making this argument, the Answer is not considering the claim as a whole and has ignored pertinent limitations. The claims require, *inter alia*, "a lead, comprising . . . an adapting member extending from the lead" Ignoring the "extending from" limitation, the Answer states that "Appellants never claim that the adapting member is unitarily formed with the lead which . . . is what Stutz and Fain do not teach." (the Answer at Page 8, line 3-5). Although Claims 1 and 9 do not require "the adapting member unitarily formed with the lead", the claims do require "an adapting member extending from the lead." The Answer's admission that Stutz and Fain lacks teaching a lead and adapting member "unitarily formed", tacitly acknowledges the validity of Appellants' position that Stutz and Fain do not teach "an adapting member extending from the lead." Accordingly, Appellants submit that, *inter alia*, the "extending from" claim limitation distinguishes Appellants' claims over Stutz in view of Fain. Therefore, a rejection under 35 U.S.C. § 103(a) is inappropriate.

In addition, the Answer contends that Fain teaches "a jumper wire embedded within the adapter interconnect[ing] the terminal block with one of the conductors insulated within the lead body." (the Answer at Page 4, lines 12 to 20). Applicants respectfully disagree. The combination of Stutz, Jr. and Fain teaches a lead plugged into an adapter that is plugged into a header assembly. Applicants disclose and claim a lead having an adapter member extending from the lead wherein a terminal block within the connector port is connected by a jumper wire to the conductors of the main lead body. Neither Fain nor Stutz teaches or suggests electrically connecting a connector port directly to a conductor within the lead body using a jumper wire. Therefore, a rejection under 35 U.S.C. § 103(a) is inappropriate because the references when combined do not teach Appellants' claimed invention.

Further, the Answer argues that Appellants' arguments in Appellants' Appeal Brief are inappropriate because one cannot show non-obviousness by attacking references individually when a combination of references is applied in the rejection. (the Answer at Page 6, lines 4-9 and at Page 9, line 17 to Page 10, line 3). At the outset, Appellants only consider the references individually when the Examiner argues obviousness citing only one reference. Further,

Appellants respectfully point out that Appellants' particular arguments are directed to the individual references and the combination of references. (Appellants' Brief, Pages 5-6, 8 and 9).

B. The References Do Not Teach, Suggest Or Motivate Their Combination.

Under sub-headings (10) Grounds for Rejection and (11) Response to Arguments, the Answer contends that combining the Fain adapter and the Stutz lead into a unitary lead and adapter "would have been an obvious engineering choice". (the Answer, Page 5, lines 5-9 and Page 8, line 10 to page 9, line 3). To support this contention and provide the motivation for the combination, the Answer expressly relies on hindsight and, alternatively, relies on In re Larson, 144 U.S.P.Q. 347 (C.C.P.A. 1965).

1. Hindsight does not form a proper basis for rejection under 35 U.S.C. §103(a).

The Examiner's use of hindsight is improper. The Answer erroneously argues that hindsight without further support is a proper basis for combining references. Particularly, the Answer argues that hindsight is proper "so long as it takes into account only knowledge which was within the level of ordinary skill at the time the invention was made, and does not include knowledge gleaned only from Appellants' disclosure." (the Answer at Page 7, lines 14-20). Examiner's position, without supporting evidence, directly opposes Federal Circuit precedent. The Federal Circuit has found that specific evidence of motivation to combine two references is necessary for a rejection under 35 U.S.C. § 103(a) to be proper. Ecolochem, Inc. v. Southern Edison, 56 U.S.P.Q.2d 1065, 1073 (Fed. Cir. 2000). Further, the Federal Circuit expressly notes that "a mere broad conclusory statement regarding the teaching of multiple references, standing alone, is not evidence." Id. (citing In re Dembiczak, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999)). The only evidence the Answer has provided is a "broad conclusory statement."

The Federal Circuit has repeatedly made clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. In re Dembiczak, 50 U.S.P.Q.2d at 1618; *see, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 48 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as

an “essential evidentiary component of an obviousness holding”); In re Rouffet, 47 U.S.P.Q.2d 1453, 1459 (Fed. Cir. 1998) (“the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them”); In re Fritch, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination “only by showing some objective teaching [leading to the combination]”); In re Fine, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion “essential” to avoid hindsight); Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 227 U.S.P.Q. 657, 667 (Fed. Cir. 1985) (district court’s conclusion of obviousness was error when it “did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination”). *See also*, Graham v. John Deere Co., 148 U.S.P.Q. 459, 467 (U.S. 1966) (“strict observance” of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *See, e.g.*, Interconnect Planning Corp. v. Feil, 227 U.S.P.Q. 543, 547 (Fed. Cir. 1985) (an invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time). The evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, Dembiczak, 50 U.S.P.Q.2d at 1618; *see also* Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 37 U.S.P.Q.2d 1626, 1630 (Fed. Cir. 1996), Para-Ordinance Mfg. v. SGS Imports Intern., Inc., 37 U.S.P.Q.2d 1237, 1240 (Fed. Cir. 1995), although “the suggestion more often comes from the teachings of the pertinent references.” Rouffet, 47 U.S.P.Q.2d at 1456. “The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular.” Dembiczak, 50 U.S.P.Q.2d at 1618, *see also*, C.R. Bard, 48 U.S.P.Q.2d at 1232. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not “evidence.” *E.g.*, McElmurry v. Arkansas Power & Light Co., 27 U.S.P.Q.2d 1129, 1131 (Fed. Cir. 1993) (“Mere denials and conclusory statements, however, are not sufficient to establish a genuine issue of material fact.”); In re Sichert, 196 U.S.P.Q. 209, 217 (C.C.P.A. 1977) (“The examiner’s conclusory statement that the specification does not teach the best mode of using the invention is unaccompanied by evidence or reasoning and is entirely inadequate to support the rejection.”). “In addition to demonstrating the propriety of an

obviousness analysis, particular factual findings regarding the suggestion, teaching, or motivation to combine serve a number of important purposes, including: (1) clear explication of the position adopted by the Examiner and the Board; (2) identification of the factual disputes, if any, between the applicant and the Board; and (3) facilitation of review on appeal.” Dembiczak, 50 U.S.P.Q.2d at 1618.

In the instant case, the Examiner has not made any particular findings regarding the suggestion, teaching, or motivation to combine the prior art references. The only finding made in the Answer to support the combination is that the Fain adapter is only operable when combined with a lead, as in Stutz. (the Answer at Page 8, line 19 to Page 9, line 3). The Answer’s limited finding undermines the above-stated purposes for requiring particular factual findings. Thus, this finding is not the particular finding required by the Federal Circuit to motivate or suggest the combination of the two cited references into Appellants’ invention. In fact, Appellants agree that the Fain adapter only operates as intended when a lead’s connector is inserted into the adapter, but Appellants do not claim a lead’s connector inserted into an adapter. Appellants claim “an adapting member extending from [a] lead . . . , wherein a jumper wire embedded within said adapting member interconnects [a] terminal block with one of the conductors insulated by the main body of the lead.” This combination is not taught by the combination of Fain and Stutz nor does Fain or Stutz suggest or motivate the combination. Nonetheless, the Answer impermissibly relies on this broad conclusory statement to support his position that the combination suggest or motivates the combination of the references into Appellants’ claimed invention.

2. The Answer’s reliance on In re Larsen is inappropriate

The Answer cites Larson to support the broad conclusory statement that an integrated construction would have been “a matter of obvious engineering choice.” (the Answer at Page 5, lines 5-9; and at Page 8, lines 1-19). Again, the Answer arrives at his conclusion without any particular finding regarding the suggestion, teaching, or motivation to combine the two references.

Regardless, the Answer’s reliance on Larson is misplaced. At the outset, the rejection in Larson was based on the teachings of a single reference teaching all claimed elements and

limitations of the invention. Therefore, whether or not there was a suggestion or motivation to combine the particular elements was presumed. The remaining question in Larson was whether or not the references taught or suggested the *manner* in which the elements were combined. No additional advantages were addressed by Larson's manner of combination. The Court found the decision of whether a particular set of parts was "integral" over "rigidly secured together" was an "obvious engineering choice." Id. at 349.

Unlike Larson, Appellants' claims are rejected over two distinct references. Neither reference alone, or in combination, teaches or suggests Appellants' invention. The Answer contends that the teaching or suggestion for combination is provided by the cited references because the Fain adapter only operates as intended when the adapter is combined with the Stutz lead. The Answer's arguments are inapposite. Again, Appellants agree that the Fain adapter only operates as intended when a lead connector is inserted into the adapter, but Appellants do not claim a lead connector inserted into an adapter. Appellants claim "an adapting member extending from [a] lead . . . , wherein a jumper wire embedded within said adapting member interconnects [a] terminal block with one of the conductors insulated by the main body of the lead." The Examiner has failed to provide any particular findings regarding the suggestion, teaching, or motivation to combine Stutz and Fain into Appellants' invention. Therefore, the Answer has not properly established a *prima facie* case of obviousness even if Larson were applicable.

As discussed above, the Answer relies on Larson when asserting that an integrated construction would have been "a matter of obvious engineering choice." (the Answer at Page 5, lines 5-9; and at Page 8, lines 1-19). However, the Answer has neglected to address Schenck v. Nortron Corp., 218 U.S.P.Q. 698 (Fed. Cir. 1993) (see M.P.E.P. § 2144.04(V)(B)). In Schenck, the Federal Circuit recognized that if additional advantages are provided by the integration of structure that the integration may not be obvious. Schenck, at 700-701. Appellants' invention provides such advantages. The integration of an adapter into a lead reduces the number of seals necessary to integrate a second lead into a single header. Reducing the number of seals decreases the complexity and decreases the likelihood of a seal failing as well as decreasing the overall size of the device. Fain teaches a header adapter for adapting the size and/or configuration of a lead connector port in the header to a different size and/or configuration of lead connector on the lead or lead being used. Further, Fain implies that two or more lead

connectors may be inserted into the header adapter lead connector ports to connect the same lead connector port to one or more leads inserted into the header adapter lead connector ports. As taught by Fain, the adapter inherently creates an increased number of seals that must be formed to isolate the patient from the electrical contacts within the adapter. That is, to accommodate two leads connected to a single header port, the header adapter must be connected to the header port and each of the leads must be connected to the header adapter's ports. Thus, three seals are necessary. With Appellants' invention in the same configuration as, the lead is connected to the header port and the second lead is attached to the lead's adapter. Thus, only two seals are necessary for the similar configuration. Neither, Stutz nor Fain recognize this problem or suggest a solution. Therefore, under Schenck, the integration of an adapter into a lead should be found non-obvious.

Similarly, In re Edge, 149 U.S.P.Q. 556 (C.C.P.A. 1966) has held that the omission of an element with retention of the elements function is an indicia of non-obviousness. (See M.P.E.P § 2144.04(II)(B)). Appellants' invention does not require a connection of an adapter in series with a lead and header (and the corresponding seals), yet retains the ability of the adapter to connect two leads to a single header connector port. Thus, In re Edge further supports Appellants position that the configuration disclosed by Appellants is non-obvious.

C. The Problem Solved Is Relevant To A Patentability Determination.

The Answer fails to properly consider the relevance of differences between the problems solved by Appellants' invention and the problems solved by the cited references. The Examiner admits his failure to understand the relevance of considering the problem solved in a patentability determination. (the Answer, Page 9, lines 9-14). Courts have found that the discovery of the source of a problem is a part of the "subject matter as a whole" inquiry which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103. In re Spinnoble, 160 U.S.P.Q. 237, 243 (C.C.P.A. 1969); *See also* In re Kaslow, 217 U.S.P.Q. 1089, 1096 (Fed. Cir. 1983); In re Peehs, 204 U.S.P.Q. 835, 837 (C.C.P.A. 1980).

In Peehs, the Court held that in order to establish a *prima facie* case of obviousness where the advance in the art lies in the discovery of the problem or the source of the problem, the examiner would have to provide evidence that a person of ordinary skill in the at the time of the invention would have expected a problem to exist. Specifically, the Court stated:

[Where] there is no evidence of record that a person of ordinary skill in the art at the time of [an applicant's] invention would have expected [a problem] . . . , it is not proper to conclude that [an invention], which solves this problem . . . would have been obvious to that hypothetical person of ordinary skill in the art. The significance of evidence that a problem was known in the prior art is, of course, that knowledge of a problem provides a reason or motivation for workers in the art to apply their skill to its solution.

Peehs, 204 U.S.P.Q. at 837 (citing In re Nomiya, 184 U.S.P.Q. 607, 612 (C.C.P.A. 1975)).

Appellant submits that neither Fain nor Stutz teaches the problems or the source of the problems that are addressed by Appellant's invention. Appellants' invention teaches a novel configuration that eliminates the need for a separate adapter and reduces the number of seals necessary when connecting multiple leads to a single port on a header. Reducing the number of seals decreases the complexity and decreases the likelihood of a seal failing as well as decreasing the overall size of the device. Fain teaches a header adapter for adapting the size and/or configuration of a lead connector port in the header to a different size and/or configuration of lead connector on the lead or lead being used. Although Fain may teach that two or more lead connectors may be inserted into the header adapter lead connector ports to connect the same lead connector port to one or more leads inserted into the header adapter lead connector ports, Fain actually teaches away from Appellants' invention by teaching the use of inactive "dummy" lead connectors that must be sealed with plugs before implantation. (Fain at Column 3, lines 54 to 56 and Column 6, lines 14 to 22). As taught by Fain, the adapter inherently creates an increased number of seals that must be formed to isolate the patient from the electrical contacts within the adapter. That is, to accommodate two leads connected to a single header port, the header adapter must be connected to the header port and each of the leads must be connected to the header adapter's ports. Thus, three seals are necessary. With Appellants' invention, the lead is connected to the header port and the second lead is attached to the lead's adapter. Thus, only two seals are necessary for the similar configuration. Neither, Stutz nor Fain teach this problem or the problem's solution. As mentioned above, Appellants disclose an invention that reduces the number and complexity of components necessary to connect multiple leads to a single port while also reducing the number of seals. Therefore, neither Stutz nor Fain teach the problem or the solution taught by Appellants' disclosure and cannot provide a proper basis for rejection of Appellants' claims.

II. THE ANSWER'S STATEMENT OF THE ISSUES IS IMPROPER.

Under sub-heading (6) Issues, the Answer states that the issue with respect to Claims 2, 4, 5, 11 and 12 is whether the claims are obvious over Stutz, Jr. in view of Fain. In prior Office Actions, the Examiner relied on Fain in view of a lead or alternatively on Fain alone as the basis for rejecting Claims 2, 4, 5, 11 and 12. (First Office Action dated October 19, 1999 and Final Office Action dated February 28, 2000 both at Page 4, lines 4 to 19). Thus, the Answer attempts to add a new basis of rejection on appeal. It has long been held that “there is no excuse for [the examiner] not positively including the reference [relied on] in the statement of rejection.” In re Hoch, 166 U.S.P.Q. 406, 407 n.3 (C.C.P.A. 1970) (See also M.P.E.P. § 706.02(j)). The M.P.E.P. requires that the Examiner should set forth “the relevant teachings of the prior art relied upon . . . , the difference or differences in the claim over the applied references . . . and an explanation of why one of ordinary skill in the art at the time the invention was made would have been motivated to make the proposed modification.” (M.P.E.P. § 706.02(j)). These requirements allow the early identification of issues and give the applicant a fair opportunity to reply. Id. The Answer by changing references relied upon during appeal has not provided Appellants an early identification of issues nor does it give Appellants the fair opportunity to reply. Therefore, Appellants submit that the statement of the issues as set forth in Appellants’ Brief is correct. Specifically, that the issue on appeal should remain obviousness under 35 U.S.C. § 103(a) over Fain and a lead with regard to Claim 2 (First Office Action dated October 19, 1999 and Final Office Action dated February 28, 2000 both at Page 4, lines 4 to 5), and obviousness under 35 U.S.C. § 103(a) over Fain with regard to Claims 4, 5, 11 and 12 (First Office Action dated October 19, 1999 and Final Office Action dated February 28, 2000 both at Page 4 lines 8 to 19).

III. THE ANSWER IMPROPERLY GROUPS THE CLAIMS.

Under sub-heading (7) Grouping of Claims, the Answer erroneously contends that Appellants have not adequately distinguished the claims such that the claims stand or fall independently. The Answer argues that merely pointing out differences in what the claims cover is not an argument as to why the claims are separately patentable. However, the Answer contradicts itself in that the Examiner has indicated that dependent claims 4, 5, 11 and 12 would

be allowable if rewritten in independent form. (the Answer at Page 2, line 12 to Page 3, line 4). Specifically, the Answer admits that “the prior art does not suggest the lead as claimed [in claims 4, 5, 11 and 12], including the aperture extending through the adapter as claimed.” (the Answer at Page 9, lines 4-8). Since the Answer admits claims 4, 5, 11 and 12 are patentable, Appellants contend that claims 4, 5, 11 and 12 stand or fall on their own merits.

The Answer contends that Claim 2 is not separately patentable. In rejecting Claim 2 as obvious, neither the Answer nor prior Office Actions state with any particularity the basis or reasoning for the rejection. (M.P.E.P. § 706.02(j)). Claim 2 is separately patentable because Claim 2 requires that the adapting member is positioned on the lead adjacent to the proximal end of the main body. The cited references when combined merely teach a lead connector inserted into an adapter connector port. Neither of the cited references, alone nor in combination, teaches or suggests an adapting member positioned on the lead adjacent to the proximal end of the main body. Therefore, Claim 2 is separately patentable and stands or falls on its own merits.

The Answer contends that Claims 6 and 13 are not separately patentable. In rejecting Claims 6 and 13 as obvious, neither the Answer nor prior Office Actions state with any particularity the basis or reasoning for the rejection. (M.P.E.P. § 706.02(j)). Claim 6 and 13 are separately patentable because Claims 6 and 13 require that the adapting member is contoured to conform to the shape of the header assembly. Neither of the cited references, alone nor in combination, teaches or suggests an adapting member contoured to conform to the header as claimed by Appellants. Therefore, Claims 6 and 13 are separately patentable and stand or fall on their own merits.

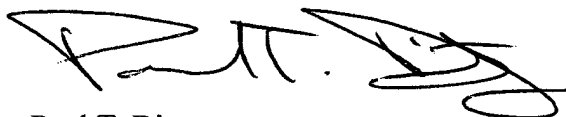
The Answer contends that Claims 7 and 14 are not separately patentable. In rejecting Claims 7 and 14 as obvious, neither the Answer nor prior Office Actions state with any particularity the basis or reasoning for the rejection. (M.P.E.P. § 706.02(j)). Claim 7 and 14 are separately patentable because Claims 7 and 14 require that the port of the adapting member is adapted for receiving a uni-polar lead. Neither of the cited references, alone nor in combination, teaches or suggests an adapter port adapted for receiving a uni-polar lead as claimed by Appellants. Therefore, Claims 7 and 14 are separately patentable and stand or fall on their own merits.

CONCLUSION

Given the differences in Appellants’ claimed subject matter and the references’ teachings,

the absence of evidence motivating one skilled in the art to combine the cited references, and the misapplication of case law to support the references' combination, there is no *prima facie* case for obviousness. Therefore, the rejection of Claims 1-15 under 35 U.S.C. § 103(a) is improper. Accordingly, a decision of the Board finding all claims patentable over the cited references is respectfully requested.

Respectfully submitted
NIKOLAI, MERSEREAU & DIETZ, P.A.

A handwritten signature in black ink, appearing to read "P.T. Dietz", with a stylized flourish at the end.

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